



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0052]

Documenting Electronic Data Files and Statistical Analysis Programs; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry (GFI) #197 entitled "Documenting Electronic Data Files and Statistical Analysis Programs." This guidance is intended to inform sponsors of recommendations for documenting electronic data files and statistical analyses submitted to the Center for Veterinary Medicine (CVM) to support new animal drug applications.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if

you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2009-D-0052 for "Documenting Electronic Data Files and Statistical Analysis Programs." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out,

will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Virginia Recta, Center for Veterinary Medicine (HFV-160), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0840, virginia.recta@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of GFI #197 entitled "Documenting Electronic Data Files and Statistical Analysis Programs." In the *Federal Register* of May 21, 2018 (83 FR 23468), FDA published the notice of availability for a draft guidance entitled "Documenting Electronic Data Files and Statistical Analysis Programs," giving interested persons until July 20, 2018, to comment on the draft guidance. On July 20, 2018, FDA published a notice of availability announcing the extension of the comment period to October 18, 2018 (83 FR 34595). FDA received numerous comments on the draft guidance and these comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated May 2018.

This guidance is intended to inform sponsors of recommendations for documenting electronic data files and statistical analyses submitted to CVM to support new animal drug applications. These recommendations are intended to reduce the number of revisions that may be required for CVM to effectively review data submissions. They are also intended to simplify submission preparation for sponsors by providing a suggested documentation framework, including a sample structure on how to describe and organize the information regarding the electronic data files and statistical analysis programs.

This Level I guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Documenting Electronic Data Files and Statistical Analysis Programs." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required.

However, this guidance refers to previously approved collections of information. These collections of information are subject to review by OMB under the PRA (44 U.S.C. 3501-3521). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910-0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry> or <https://www.regulations.gov>.

Dated: November 9, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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